



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,551	02/05/2002	Jeffrey E. Thomas	26998.2	8294

570 7590 09/12/2003

AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 09/12/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,551

Applicant(s)

THOMAS, JEFFREY E.

Examiner

Cris L. Rodriguez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-70 and 72-74 is/are pending in the application.
- 4a) Of the above claim(s) 65-70, 72 and 74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 73 is/are allowed.
- 6) ☒ Claim(s) 51, 54-60 and 64 is/are rejected.
- 7) ☒ Claim(s) 52, 53 and 61-63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, species b) figures 6C-6E, claims 51-64, and 73 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that it would have not been a serious burden to search for species a and b, (claims 51-64, 72, and 73 will uncover references directed toward the species including figures 6A-6B as well as the species including Figures 6C and 6E, since the elements called for in claims 57-60 can be configured as shown in the embodiment of figures 6C-6E), and thus claim 51 is generic to both species as set forth in the office action. This is not found persuasive because the fact that a claim does so read in several species is not conclusive that it is generic. It may define only an element or subcombination common to the several species. (MPEP 806.04(d and e)). Furthermore, Applicant's disclosure set forth that both are different species.

The requirement is still deemed proper and is therefore made FINAL.

2. Please note that claim 72 has been withdrawn from consideration by the examiner as being drawn to a non-elected species. The elected species does not show a multi-way valve.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the instructional material as set forth in claim 73 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Art Unit: 3763

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 57 is indefinite because it is not clear from the claim and the drawings how the second hollow body (line 1) contains the at least one compartment when in figure 6E is shown that the first hollow body is the one that has the compartment.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 51, 54, 57, 60, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelsher et al (US 3,570,486).

Engelsher discloses a syringe device for delivering a medicament having a first hollow body 12 with a flow orifice (chamber 30), a first fluid access port 18, and a first pressure orifice at the rear end portion of body 12. A second hollow body 68 having a

Art Unit: 3763

second fluid access port 52 in fluid communication with the interior of the second hollow body and in fluid communication with the first access port, and an outlet port 64,66 in fluid communication with the interior of the second hollow body, and a first pressure modulator 28 connected to the first pressure orifice.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelsher.

Engelsher discloses the invention substantially as claimed. However, Engelsher fails to disclose the pharmacological agent being nitric oxide donor compound, or a single human intrathecal delivery amount of the nitric oxide donor compound. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one pharmacological agent for another since Engelsher is capable of delivering a medicament to a patient.

Allowable Subject Matter

10. Claims 52, 53, and 61-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3763

11. Claims 58 and 59 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
12. Claim 73 is allowable over the prior art of record.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See 892-form.

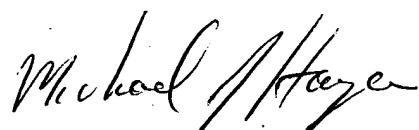
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

September 2, 2003


Cris L. Rodriguez
Examiner
Art Unit 3763


MICHAEL J. HAYES
PRIMARY EXAMINER